

POLICY AND COMMUNICATIONS BULLETIN

THE CLINICAL CENTER

Medical Administrative Series

M92-20 (rev.)

7 October 1997

MANUAL TRANSMITTAL SHEET

SUBJECT: Policy on Voluntary Sterilization of Clinical Center Patients

1. Explanation of Material Transmitted: This issuance transmits a revised policy of the Clinical Center regarding the voluntary sterilization of patients in the Warren Grant Magnuson Clinical Center. This policy was reviewed by the Medical Executive Committee on 7 October 1997 and approved with the deletion of the attached consent document, which no longer complied with federal regulations 42 CFR 50.203.
2. Material Superseded: MAS No. M92-20, dated 1 December 1992
3. Filing Instructions: Informed Consent Section

Remove: No. M92-20, dated 1 December 1992

Insert: No. M92-20 (rev.), dated 7 October 1997

DISTRIBUTION

Physicians, Dentists and Other Practitioners Participating in Patient Care

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POLICY

Surgical sterilizations may be performed on patients in the Warren Grant Magnuson Clinical Center as a part of an approved protocol, incident to another surgical procedure, or when necessary to protect the patient from death or serious harm. Such sterilizations will be carried out in accordance with the guidelines enumerated in this policy statement.

GUIDELINES

1. Surgical sterilizations performed at the Clinical Center shall meet the legal requirements prescribed by in 42 CFR 50.203. They are:
 - a. Informed consent has voluntarily been given by the patient, who is at least 21 years of age and mentally competent.
 - b. The sterilization is performed no less than 30 days nor more than 180 days after informed consent has been given. However, in the case of premature delivery or emergency abdominal surgery, an individual may consent to be sterilized at the time of operation if at least 72 hours have passed since informed consent was obtained. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.

- c. A consent document as iterated in the HHS regulations at 42 CFR, Part 50, Subpart B, Appendix, is completed.
- 2. Sterilizations may be done as a part of an approved protocol. Individuals requesting sterilization under these circumstances will have independently decided to undergo this procedure; they will be referred to the Clinical Center when their personal physicians believe they are suitable for inclusion in an appropriate study.
- 3. Patients may request sterilization incident to the performance of another abdominal operation.
- 4. Sterilization not done as a part of an approved protocol or another abdominal operation may be performed with the informed consent of a mentally competent patient who is at least 21 years of age, when in the medical judgment of the attending physician the procedure is necessary to protect the patient from significant harm or death. In such cases, approval must be obtained from the Director or Deputy Director for Clinical Care, Clinical Center, after consultation with the NIH Legal Advisor's office.
- 5. A copy of this policy, the regulations, and necessary consent documents are available at each patient care unit and in the Operating Room.